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**REMARKS**

Claims 116-119 were pending in the subject application. Applicant has hereinabove canceled claims 116-119 without disclaimer or prejudice to applicants' right to pursue the subject matter of these claims in the future. Instead, applicants added new claims 127-129. Accordingly, upon entry of this Amendment, claims 127-129 will be pending and under examination.

Applicants maintain that new claims 127-129, are fully supported by the specification as originally filed. Support for new claim 127 may be found, *inter alia*, in the specification as follows: page 23, lines 9-29; page 22, lines 9-11; page 30, lines 5-11 and lines 29-33; page 31, lines 14-16; page 32, lines 24-32; page 53, line 20 to page 54, line 1; page 55, lines 5-16; and Figs. 14-16. Support for new claims 128 and 129 may be found, *inter alia*, in the specification as follows: page 23, lines 9-29; page 22, lines 9-11; page 30, lines 5-11 and lines 29-33; page 31, lines 14-16; page 32, lines 24-32; page 53, line 20 to page 54, line 1; page 55, lines 5-16; and Figs. 14-16. Accordingly, entry of this Amendment is respectfully requested.

**Obviousness-Type Double Patenting Rejection**

In the May 23, 2005 Office Action the Examiner rejected claims 116-119 as allegedly obvious over claims 1-13 of U.S. Patent No. 5,538,866 (the '866 patent) in view of Lerner.

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In response, applicants note that claims 116-119 have been cancelled, thereby rendering the Examiner's rejection moot. Moreover, applicants maintain that this rejection cannot apply to new claims 127-129 for reasons that follow.

According to M.P.E.P. §804(B)(1), "[a] double patenting rejection of the obviousness-type is 'analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103' except that the patent principally underlying the double patenting rejection is not considered prior art." *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, the analysis parallels the guidelines for a 35 U.S.C. §103(a) rejection including the requirements for establishing a *prima facie* case of obviousness. See *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985). Applicants maintain that the Examiner has not established a *prima facie* case of obviousness for new claims 127-129 over claims 1-13 of the '866 patent in view of Lerner.

New claim 127 provides, in part, "[a]n isolated nucleic acid having within its structure at least 15 consecutive nucleotides present in the sequence set forth in SEQ ID NO:1". As the Examiner indicates on page 3 of the May 23, 2005 Office Action, the '866 patented claims "do not teach 15-mer or longer nucleic acid fragments of PSMA". Applicants note that the isolated nucleic acid of claim 1 of the '866 patent is a degenerate nucleic acid encoding a prostate specific membrane antigen. Applicants maintain that the subject matter of new claim 127 is therefore a species within the genus of claim 1 of the '866 patent.

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According to M.P.E.P. § 2144.08, when determining whether claims directed to species are *obvious* over a genus, a *prima facie* case of obviousness must first be established. The fact that a claimed species is encompassed by a patented genus is not sufficient by itself to establish a *prima facie* case of obviousness. *In re Baird*, 16 F.3d 380, 382; 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). Therefore, applicants maintain that the currently claimed species of new claim 127 is not rendered obvious by the previously patented genus of claim 1 of the '866 patent.

Applicants further maintain that the recited specific sequence, i.e. SEQ ID NO:1, of new claim 127, cannot be obvious over the degenerate nucleic acid of claim 1 of the '866 patent in view of Lerner. It is well established knowledge that an amino acid sequence such as the recited amino acid sequence SEQ ID NO:2 in claim 1 of the '866 patent may be encoded by more than one nucleic acid sequence. According to M.P.E.P. §2144.09, this established relationship between a nucleic acid and the protein it encodes does not, as a matter of law, render the nucleic acid *prima facie* obvious over the encoded protein because of the degeneracy of the genetic code. See *In re Deuel*, 51 F.3d 1552, 34 USPQ2d 1210 (Fed Cir. 1995). Accordingly, the specific nucleic acid sequence recited in new claim 127 is not obvious over claim 1 of the '866 patent.

Applicants also note that the '866 patent claims do not teach or suggest nucleic acids encoding a *fragment* of the prostate specific membrane antigen, and Lerner does not cure this deficiency. Furthermore, the claimed nucleic

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acid of new claim 127 encodes a specific portion of the outside region of prostate specific membrane antigen, or all the outside region, which is not claimed in the '866 patent and not obvious over the claims of the '866 patent alone or in combination with Lerner.

New claim 128 provides, in part, "[a]n isolated nucleic acid having within its structure at least 15 consecutive nucleotides". As stated above, the Examiner indicates that the '866 patented claims "do not teach 15-mer or longer nucleic acid fragments of PSMA". Applicants maintain that the subject matter of new claim 128 is a species within the genus of claim 1 of the '866 patent. Accordingly, as discussed above, applicants maintain that the currently claimed species of new claim 128 also is not obvious over the previously patented genus of claim 1 of the '866 patent.

Applicants note that there is no claim in the '866 patent directed to a fragment of PSMA, and no apparent reasoning as to why such a fragment would be obvious to one of skill in the art in view of Lerner is set forth. In addition, there is no claim to a nucleic acid encoding a fragment of PSMA specified as its entire outside region, a deficiency not cured in view of Lerner. Thus, applicants maintain that new claim 128 is not obvious over the claims of the '866 patent alone or in combination with Lerner.

New claim 129 further defines the nucleic acid of new claim 128 as having "a sequence which is present within the sequence set forth in SEQ ID NO:1". As discussed

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above, the recited specific sequence, i.e. SEQ ID NO:1, is not obvious over the nucleic acids of claim 1 of the '866 patent in view of Lerner. Accordingly, applicants maintain that none of new claims 127-129 are obvious over claims 1-13 of the '866 patent alone or in view of Lerner, and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

In the May 23, 2005 Office Action, the Examiner also rejected claims 116-119 as allegedly obvious over claims 1-10 of U.S. Patent No. 5,935,818 (the '818 patent) in view of Lerner.

In response, applicants note that claims 116-119 have been cancelled, thereby rendering the Examiner's rejection moot. Moreover, applicants maintain that this rejection cannot apply to new claims 127-129 for reasons that follow.

As discussed above, the analysis for a double patenting rejection parallels the guidelines for a 35 U.S.C. §103(a) rejection including the requirements for establishing a *prima facie* case of obviousness. Applicants again maintain that the Examiner has not established a *prima facie* case of obviousness for new claims 127-129 over claims 1-10 of the '818 patent in view of Lerner.

Again, new claim 127 provides, in part, "[a]n isolated nucleic acid having within its structure at least 15 consecutive nucleotides present in the sequence set forth in SEQ ID NO:1". As the Examiner indicates on page 3 of the May 23, 2005 Office Action, the '818 patented claims

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"do not teach 15-mer or longer nucleic acid fragments of PSMA". Applicants note that the isolated nucleic acid of claim 1 of the '818 patent is a degenerate nucleic acid encoding an alternatively spliced prostate specific membrane antigen having an "amino acid sequence consisting of the sequence as set forth in SEQ ID NO:2 beginning with methionine at position number 58". Applicants maintain that the nucleic acid of new claim 127 "has a sequence which is the same as a sequence of all or less than all of an outside region of prostate specific membrane antigen, the amino acid sequence of which outside region is set forth within SEQ ID NO:2 beginning with amino acid number 45 at the amino terminus and ending with amino acid number 750 at the carboxy terminus". Accordingly, the nucleic acid of claim 1 of the '818 patent does not teach a nucleic acid encoding the first 13 amino acid residues of the protein encoded by the nucleic acid as claimed in new claim 127.

Moreover, claim 1 of the '818 patent is directed to degenerate nucleic acids and thus does not provide, or make obvious, the specific nucleic acid of SEQ ID NO:1. Accordingly, new claim 127 is not obvious over the claims of the '818 patent, alone or in combination with Lerner.

With regard to new claim 128, applicants note that there is no claim in the '818 patent that is directed to the nucleic acid sequence encoding the specific fragment of PSMA as set forth in the claim, i.e. a fragment having a sequence which is the same as a sequence of all of an outside region of prostate specific membrane antigen, the amino acid sequence of which outside region is set forth

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within SEQ ID NO:2 beginning with amino acid number 45 at the amino terminus and ending with amino acid number 750 at the carboxy terminus. In addition, no apparent suggestion or reasoning is set forth as to why such a fragment would be obvious to one of skill in the art. Thus, new claim 128 is not obvious over the claims of the '818 patent alone or in combination with Lerner.

As also discussed above, new claim 129 further defines the nucleic acid of new claim 128 as having "a sequence which is present within the sequence set forth in SEQ ID NO:1", which specific sequence is not obvious over the nucleic acids of claim 1 of the '818 patent in view of Lerner.

Accordingly, applicants maintain that none of new claims 127-129 are obvious over claims 1-10 of the '818 patent alone or in view of Lerner, and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

#### **Summary**

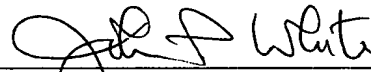
Applicants maintain that the new claims 127-129 are in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone conference would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

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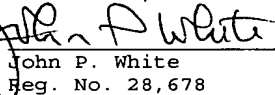
No fee, other than the \$510.00 fee for a three-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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